IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF WISCONSIN

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GEORGE H. PETERS,

Plaintiff,

v.

ASTRAZENECA, LP and
PROCTER & GAMBLE DISTRIBUTING COMPANY,

Defendants.

OPINION AND ORDER

05-C-649-C

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Plaintiff George H. Peters, an inmate at the New Lisbon Correctional Facility in New Lisbon, Wisconsin, filed this products liability action originally in the United States District Court for the Eastern District of Wisconsin. The case was transferred to this court pursuant to 28 U.S.C. § 1406(a). In this action, plaintiff contends that he lost his sense of taste after taking omeprazole, a drug marketed and distributed by defendants, AstraZeneca, LP and Procter & Gamble Distributing Co., under the brand name Prilosec. Plaintiff seeks compensatory and punitive damages based on state common law claims of strict liability and negligence for defective product design and failure to warn. Federal subject matter jurisdiction is present under 28 U.S.C. § 1332.

Now before the court are defendants' motion to dismiss plaintiff's claims pursuant to Fed. R. Civ. P. 12(b)(6), and defendants' motion to stay discovery. Defendants' first motion raises questions whether Food and Drug Administration regulations preempt plaintiff's state common law claims and whether the court should abstain from hearing this case in deference to the FDA's primary jurisdiction and expertise. I conclude that plaintiff's claims are not preempted by FDA regulations and that the doctrine of primary jurisdiction does not apply to this case; therefore, defendants' motion to dismiss will be denied. Defendants' motion to stay discovery will be denied as moot.

For the purpose of deciding defendants' motion to dismiss, I draw the following facts from plaintiff's amended complaint.

ALLEGATIONS OF FACT

Beginning in November 2003, plaintiff purchased and consumed omeprazole, an over-the-counter drug sold under the brand name Prilosec. He purchased and used over-the-counter Prilosec in Oklahoma during 2003 and "had the drug prescribed by a physician in Portage and New Lisbon, Wisconsin." (Presumably, because plaintiff is an inmate at the New Lisbon Correctional Facility in Wisconsin, he needed a prescription even for an over-the-counter drug.) Plaintiff continued to take over-the-counter Prilosec until January 2005 for treatment of stomach acid reflux disease. His consumption of Prilosec caused "special

senses" damage to his tongue. Specifically, his tongue has become numb and he is unable to taste food.

Defendants were aware that over-the-counter Prilosec could cause damage to a consumer's special senses (that is, numbness of tongue, taste perversion, and taste loss), but failed to adequately warn consumers of these harmful side effects. No warning relating to special senses damages was included in the product package for over-the-counter Prilosec. Had he been adequately and appropriately advised, notified, and warned that there was a possibility of injury from the use of Prilosec, plaintiff "would have utilized other medical procedures."

OPINION

In their motion to dismiss, defendants contend that plaintiff's claims are preempted by federal law and the regulatory authority of the FDA. Alternatively, defendants argue that the court should abstain from hearing this case in deference to the FDA's primary jurisdiction and expertise.

As a preliminary matter, I note that in their reply brief, defendants raised for the first time an additional argument that the "learned intermediary" doctrine should preclude plaintiff's claims in this case. Defs.' Reply Br., at 4. They contend that because Prilosec was prescribed to plaintiff by his physician and the drug's adverse side effects were imparted to

the treating physician in the Physician's Desk Reference, the learned intermediary doctrine absolves them of liability. As a general rule, arguments not raised until the reply brief are deemed waived. Carter v. Tennant Co., 383 F.3d 673, 679 (7th Cir. 2004) (citing APS Sports Collectibles, Inc. v. Sports Time, Inc., 299 F.3d 624, 631 (7th Cir. 2002)). In any event, the argument would not succeed even if it had been raised properly. As the defendants concede, the Supreme Court of Wisconsin has not had occasion to decide the applicability of the learned intermediary doctrine as it applies to drug manufacturers in Wisconsin, Defs.' Reply Br., at 4 n.1, and no Wisconsin appellate court has adopted the doctrine, see, e.g., Kurer v. Parke, Davis & Co., 2004 WI App. 74, ¶ 21, 272 Wis. 2d 390, 679 N.W.2d 867 (declining to decide whether the learned intermediary doctrine applies to medications prescribed for extended time periods). This court will not create Wisconsin law without some indication that the state's highest court would apply the doctrine if given the opportunity to do so.

In deciding defendants' motion to dismiss, the court must accept as true all well-pleaded facts alleged in the complaint and draw all reasonable inferences in favor of the plaintiff. McMath v. City of Gary, 976 F.2d 1026, 1031 (7th Cir. 1992); Craigs, Inc. v. General Electric Corp., 12 F.3d 686, 688 (7th Cir. 1993). Dismissal is proper only when it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations. Kunik v. Racine County, Wis., 946 F.2d 1574, 1579 (7th

Cir. 1991).

A. Preemption

The United States Constitution provides that the laws of the United States "shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. This means that federal laws or regulations may preempt state laws that interfere with, or are contrary to, federal laws. Hillsborough County v. Automated Med. Labs, Inc., 471 U.S. 707, 712 (1985). There are three different ways a federal law may preempt state law:

> First, when acting within constitutional limits, Congress is empowered to pre-empt state law by so stating in express terms. In the absence of express pre-emptive language, Congress' intent to pre-empt all state law in a particular area may be inferred where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress left no room for supplementary state regulation. Pre-emption of a whole field also will be inferred where the field is one in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.
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> Even where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent that it actually conflicts with federal law. Such a conflict arises when compliance with both federal and state regulations is a physical impossibility, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Id. at 712-13 (internal citations and quotations omitted). Here, express preemption is not at issue; field and conflict preemption are.

1. Field preemption

Defendants contend that plaintiff's claims are preempted because the "FDA [drug labeling] process so thoroughly occupies the legislative field that it may be reasonably inferred that Congress left no room for state product liability law to supplement it." Defs.' Motion at 7. The party contending that a claim is preempted bears the burden of establishing preemption. In the absence of express preemption, there is a basic assumption that Congress did not intend to displace state law. See, e.g., Maryland v. Louisiana, 451 U.S. 725, 746 (1981). This presumption is even stronger where the federal legislation or regulations involve areas the states have traditionally occupied. Courts must presume that the historic police powers of the states should not be superseded unless there is a clear and manifest purpose of Congress. Geier v. Am. Honda Motor Co., 529 U.S. 861, 907 (2000). Protecting health and safety is an area traditionally occupied by the states. Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) (noting "the historic primacy of state regulation of matters of health and safety"); Ophthalmic Mut. Ins. Co. v. Musser, 143 F.3d 1062, 1066 (7th Cir. 1998). Therefore, the duty Wisconsin law imposes upon manufacturers of dangerous products to warn individuals of the product's dangers falls within the state's traditional role of protecting the health and safety of its citizens. Accordingly, this court must apply the anti-preemption presumption absent "clear evidence" of an intent on the part of Congress or the FDA to preempt state products liability claims. See, e.g., Buckman Co.

v. Plaintiffs' Legal Comm., 531 U.S. 341, 352 (2001); Geier, 529 U.S. at 885; Hillsborough, 471 U.S. at 715.

Defendants have failed to cite any authority supporting their theory that the FDA drug labeling process "so thoroughly occupies the legislative field that it may be reasonably inferred that Congress left no room for state product liability law to supplement it." Defs.' Br., at 7. Defendants cite § 379r of the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 379r, which relates to national uniformity of nonprescription drugs, but do not explain how this statute advances their argument regarding field preemption. In fact, defendants concede that 21 U.S.C. § 379r(e) provides an exception for state product liability laws. Defs.' Br., at 6 n.2. Specifically, § 379r(e) provides, "Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." Section 379r(e) leaves room explicitly for state product liability laws to supplement the drug labeling process. Therefore, in the context of product liability, it is clear that Congress did not intend to occupy the legislative field so thoroughly as to preempt plaintiff's claims.

This finding is consistent with Wisconsin's view that "a drug manufacturer's compliance with the FDA's labeling requirements does not preempt state-law claims." Kurer, 2004 WI App. 74, ¶ 19. FDA drug labeling requirements impose only "minimum standards" that are open to supplementation by state law. Id., ¶ 21; see also, Wells v. Ortho

Pharmaceutical Corp., 788 F.2d 741, 746 (11th Cir. 1986) ("An FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes."); Hill v. Searle Labs, 884 F.2d 1064, 1068 (8th Cir. 1989) ("FDA approval is not a shield to liability . . . . FDA regulations are generally minimum standards of conduct unless Congress intended to preempt common law, which Congress has not done in this area."); Kociemba v. Searle & Co., 680 F. Supp. 1293, 1299 (D. Minn. 1988); Mazur v. Merck & Co., 742 F. Supp. 239, 247 (E.D. Pa. 1990); Motus v. Pfizer Inc., 127 F. Supp. 2d 1085, 1092 (C.D. Ca. 2000).

2. Conflict premption

Similarly, defendants have failed to overcome the anti-preemption presumption by showing clear evidence that plaintiff's claims should be preempted because they present a direct conflict with federal law. In order to prove a conflict, defendants must show either (1) it is impossible for an individual to comply with both the challenged state law (in this case, a common law duty to adequately warn patients taking over-the-counter Prilosec of the risks of taking the drug) and federal law; or (2) the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. See, e.g., Crosby v. National Foreign Trade Council, 530 U.S. 363, 37273 (2000); Hillsborough County, 471 U.S. at 712. Defendants have not made either of these showings.

In support of their argument that plaintiff's claims are preempted, defendants cite Needleman v. Pfizer, Inc., 2004 WL 1773697 (N.D. Tex April 6, 2004) and Dusek v. Pfizer, Inc., 2004 WL 2191804 (S.D. Tex. Feb. 20, 2004), two federal cases in which the district courts found preemption based on a conflict between Texas state law and FDA regulations. However, as the defendants recognize in their brief, those cases were decided on motions for summary judgment made after a sufficient factual record was developed. More to the point, those courts did not make the broad finding of an implicit preemption of state law tort claims based on a failure to warn theory. Rather, both courts found preemption of state requirements *actually conflicting* with a standard implemented by the FDA. Needleman, 2004 WL 1773697, at * 2; Dusek, 2004 WL 2191804, at *5.

In those cases, the courts based their determination whether a state requirement actually conflicted with a standard implemented by the FDA on a detailed review of the factual record. See id. In Needleman, the court found that the FDA had clearly determined that an additional warning on a drug would be false, misleading, and harmful to patients. Needleman, 2004 WL 1773697, at *2, *5. In Dusek, the court found that the FDA had explicitly rejected an additional warning on a drug that the plaintiff requested and that the additional warnings would be false and misleading. Dusek, 2004 WL 2191804, at *9. Thus, the court found that inadequate warning claims would actually conflict with federal requirements.

In this motion to dismiss, there is no such factual record evidencing an actual conflict. The mere fact that the FDA does not require a warning on a product label does not necessarily create a conflict. As explained above, FDA requirements impose only minimum standards that are open to supplementation by state law. Drawing all reasonable inferences in favor of the plaintiff, I find that plaintiff's product liability claims are not preempted based on the facts alleged in his amended complaint.

B. Abstention

Next, defendants argue that the court should abstain from deciding this case in deference to the "primary jurisdiction" of the FDA. Defs.' Br., at 9. The doctrine of primary jurisdiction is concerned with promoting proper relationships between the courts and administrative agencies charged with particular regulatory duties and applies where a claim that is originally cognizable in courts "requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body," United States v. Western Pacific R.R. Co., 352 U.S. 59, 63-64 (1956). In deciding whether to apply the primary jurisdiction doctrine, a court should take into account the doctrine's two primary interests: resolving technical questions of fact through an agency's specialized expertise prior to judicial consideration of the legal claims and consistency and uniformity in the regulation of an area which Congress has entrusted to a specific agency.

See, e.g., Nader v. Allegheny Airlines, Inc., 426 U.S. 290, 303-04 (1976). In the past, the doctrine has been applied in matters that required the FDA's special expertise to resolve an issue in the first instance. See, e.g., Rutherford v. Am. Med. Ass'n, 379 F.2d 641 (7th Cir. 1967); Tutoki v. Celebrezze, 375 F.2d 105 (7th Cir. 1967). For example, in Rutherford, 379 F.2d at 643, the Seventh Circuit invoked the primary jurisdiction doctrine because an essential element of the case required a showing that the drug in question would have been approved or exempted by the FDA. Until the FDA acted on an application for approval or exemption of the drug, judicial review was not appropriate. Id.

In this case, it is unclear what issues, if any, defendants want the FDA to resolve. In their reply brief, defendants allege that the FDA considered whether to require defendants to warn against special senses damages, but decided not to require that warning when it approved Prilosec for over-the-counter sale. Defs.' Reply Br., at 2-3. Even assuming that this is true, it demonstrates only that the FDA has already had an opportunity to pass on the issue in the first instance. However, "[a]n FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes." Kurer, 2004 WI App. 74 , ¶ 21 (citing Wells, 788 F.2d at 746).

Furthermore, plaintiff's claims are grounded in state tort law. Although the issues plaintiff raises require some technical analysis, questions such as whether Prilosec is a defective product, whether defendants breached any duties owed to the plaintiff by failing

to give adequate warnings and whether the plaintiff's injuries were caused by defendants' conduct are legal questions that fall within the conventional experience of judges, not administrative agencies. Defendants fail to show how this case is any different from the thousands of other personal injury suits regularly decided by courts.

Finally, plaintiff seeks monetary damages only. A court may refuse to invoke primary jurisdiction when a plaintiff is seeking damages for injury to his property or person, as this is the type of relief courts routinely evaluate. Ryan v. Chemlawn Corp., 935 F.2d 129, 131 (7th Cir. 1991) (lower court improperly invoked primary jurisdiction doctrine when plaintiff sought monetary damages only). The FDA does not have authority to grant the compensatory or punitive damages sought by plaintiff in this case.

Because I do not find that the doctrine of primary jurisdiction is applicable to this case, defendants' motion to dismiss will be denied with respect to their request that the court abstain from hearing this case in deference to the FDA.

ORDER

IT IS ORDERED THAT

1. The motion of defendants AstraZeneca, LP and Procter & Gamble Distributing Co. to dismiss is DENIED.

2. Defendants' motion to stay discovery is DENIED as moot.

Entered this 3d day of March, 2006.

BY THE COURT:
/s/
BARBARA B. CRABB
District Judge